NOBASET®

X-Ray Gehörgangtupfer

REF 639115 (as of LOT 35834)

Contents of this procedure pack:

10 x X-Ray Gehörgangtupfer (X-ray auditory meatus swab) L, NOBAMED Paul Danz AG, MD CE 123

1 x Schale (plastic bowl), NOBAMED Paul Danz AG, MD CE

1 x NOBAWRAP®, NOBAMED Paul Danz AG MD CE

Product Description, Intended use, Application
The sterile procedure pack consists of 10 x-ray auditory meatus swabs, NOBAWRAP® as sterile underlay and a bowl for keeping the swabs until there are used on the patient. The swabs are suited for ear operation due to their pointed shape. In the area of the auditory canal, their pointed shape is especially of advantage. They are used for the absorption of blood and wound fluids.

Composition
Auditory meatus swab: Cotton, x-ray thread made of barium sulphate, PVC, DOTP, plastic bowl: PET, NOBAWRAP®: Cellulose, polyethylene,

Contra-Indications
The product should not be used in the case of a known allergy against the material.

This product is for single and temporary use on one patient and must be applied by specially trained medical personnel. Any information for use that is available for individual products must be observed!

Normative and Legal Requirements
Procedure Pack according to Art. 22, Medical Device Regulation (EU) 2017/745, risk class IIa.

The compatibility of the customized medical devices or other products has been assessed with due regard for the indications of the

respective manufacturers, and operations have been performed in accordance with the aforementioned indications.
The manufacturers' intended use is not changed.
The systems and procedure packs are packed in compliance with a validated procedure.

All activity is properly monitored and controlled as part of our QM system, in accordance with DIN EN ISO 13485:2016.

A validated sterilization process is used for sterile procedure packs, taking into account the manufacturers' instructions, so that product functionality and product safety of the components are maintained after a system or procedure pack has been compiled and sterilized.

Sterilization and packaging are subject to supervision of our Notified Body TÜV Süd PS 0123 pursuant to Annex XI, Part A.

The gauze complies with the requirements of DIN EN 14079 type 20.
The product does not contain dangerous toxic substances according to REACH. It has CE marking and DIN EN ISO 15223-1 labels on all its packaging.

Storage and transport
To be stored in a dry and dust-free environment, protected from sunlight

The product bears following labels and symbols

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